



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,664	08/19/2003	John N. Semertzides	18913/0507308	5748

26874 7590 04/03/2008
FROST BROWN TODD, LLC
2200 PNC CENTER
201 E. FIFTH STREET
CINCINNATI, OH 45202

EXAMINER

FISHER, ABIGAIL L

ART UNIT	PAPER NUMBER
----------	--------------

1616

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

04/03/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com
rgaunce@fbtlaw.com

Office Action Summary	Application No. 10/643,664	Applicant(s) SEMERTZIDES ET AL.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 28, 29 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 28, 29, 33, 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Request for Continued Examination and Amendments/Remarks filed on December 3 2007 is acknowledged. Claims 1-20, 22-27 and 30-32 stand cancelled. Claim 21 was amended. Claims 21, 28-29, and 33-36 are pending. Claims 34 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 4 2007. It is additionally noted that the Applicant has previously elected the abdomen as the loci. Claims 21, 28-29, 33, and 35 are directed to the elected invention.

Withdrawn Rejections

The rejection of claims 21, 28-29, 33, and 35 under 35 USC 103(a) as being unpatentable over WO 96/22115 in view of MacLaughlin et al. (US Patent No. 6692738) is withdrawn in light of applicant's amendments filed on December 3 2007.

The following represents all new grounds of rejection presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 28-29, 33 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 as written is vague and indefinite. The claim as written indicates "animal or human pelvis, abdomen, thorax..." It is unclear if the claim is directed animal pelvis, animal abdomen, animal thorax, etc. and human pelvis, human abdomen, human thorax, etc. Alternatively, is the claim directed to animal or human pelvis and then any species of abdomen, thorax, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 28, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (Plastic and Reconstructive Surgery, 2001, cited on PTO Form 1449) in view of Sawhney et al. (US Patent No. 5900245).

Applicant Claims

Applicant claims a method for the treatment and prevention of adhesions in a patient comprising surgically accessing the animal or human where an adhesion(s) have formed or may form; dividing one or more adhesions that may be present or conducting other surgery, thereby forming an injured area; providing viable epithelial cells and an absorbable protein; and applying said cells and protein in one more layers in the form of a liquid, paste or gel directly to said injured area, without the use of scaffolding to stabilize and temporarily separate the injured area from the surrounding organ surfaces.

A further limitation is that the viable epithelial cells are harvested from a body cavity.

A specific absorbable protein claimed is fibrin glue.

The cells and protein are admixed prior to application to the injured area and the admixture is applied to the injured area.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Cohen et al. is directed to aerosol comprising epidermal cells with fibrin glue. Cell suspensions were prepared from the groin area of each hind leg (page 1210, cell suspension preparation). Wounds were created over each of the pig's backs. Following wound creation, retraction of the edges was observed. The wounds were then sprayed with a suspension of the epidermal cells with fibrin glue resulting in epithelialization. It is indicated that the combination of the fibrin glue and epidermal cells enhances epithelialization of wounds with unfavorable topography in pigs.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Cohen et al. does not specify the treating of different types of wounds such as the elected species, abdomen. However, this deficiency is cured by Sawhney et al.

Sawhney et al. discloses that fibrin glue is well known for making bonds for sealing a tissue or organ (column 2, lines 1-12). Examples of medical conditions which require this type of coating or sealing includes sealing lung tissue against air leakage, closing wounds, barriers to prevent post-surgical adhesions including those of the pelvis and abdomen, pericardium, spinal cord and dura, tendon and tendon sheath, treating exposed skin, or in the repair or healing on incisions, abrasions, etc. (columns 13-14, lines 65-67 and 1-17).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cohen et al. and Sawhney et al. and utilize the composition of Cohen et al. in other type of wounds such as post-surgical wounds of the abdomen. One of ordinary skill in the art would have been motivated to utilize the composition of Cohen et al. to treat post-surgical wounds of the abdomen because Sawhney et al. discloses that fibrin glue is known to be utilized for this reason. Additionally, Cohen et al. indicates that the composition is beneficial for wounds with unfavorable topography which is the type of topography one of ordinary skill in the art would expect with a post-surgical wound.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. in view of Sawhney et al. in further view of Stedman's Medical Dictionary (1995).

Applicant Claims

Applicant claims that the viable epithelial cells are harvested from the mouth or oral cavity.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Cohen et al. and Sawhney et al. are set forth above. Specifically, Cohen et al. teaches isolating epidermal cells from groin area of each hind leg.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Cohen et al. does not specify isolating epidermal cells or epithelial cells from other locations. However, this deficiency is cured by Stedman's Medical Dictionary.

Stedman's Medical Dictionary that epithelium is the cellular layer covering all the free surfaces, cutaneous, mucous, and serous, including the glands and other structures derived therefrom.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cohen et al. and Stedman's Medical Dictionary and utilize viable cells from other portions of the body. Obtaining the same type of cells from different parts of the body still results in harvesting the same type of cells. Therefore, it would have been obvious to one of ordinary skill in the art to harvest epithelial cells from either a cutaneous, mucous such as the mouth, or serous source, which are known sources of epithelial cells, resulting in the practice of the instant application with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Sharmila Gollamudi Landau/

Primary Examiner, Art Unit 1611